UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALFRED SCHMIDT and HEINRICH WIELAND

Appeal No. 2004-2105
Application No. 09/646,355

HEARD: January 27, 2005

Before WILLIAM F. SMITH, SCHEINER, and GREEN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 17-24, all the claims pending in the application. Claim 17 is representative of the subject matter on appeal and reads as follows:

17. A method of making a medicament for the prophylaxis or treatment of mastocarcinoma, comprising combining a therapeutically or prophylactically effective amount of an active ingredient comprising a steroidal aromatase inhibitor and containing no antigestagens and a substance for promoting skin penetration so as to avoid systemic action of the active ingredient.

The references relied upon by the examiner are:

Messenger	WO 96/08231	Mar. 21, 1996

(PCT Application)

Brodie et al. (Brodie), "Aromatase Inhibitors III, Studies on the Antifertility Effect of 4-Acetoxy-4-androstene-3, 17-dione," Biology of Reproduction, Vol. 18, pp. 365-370 (1978)

Remington: The Science and Practice of Pharmacy, (Remington) 19th ed., p. 1218 (1995)

Claims 17-24 stand rejected under 35 U.S.C. § 103(a). The examiner relies upon Messenger, Brodie, and Hanson as evidence of obviousness. We affirm.

Discussion

Appellants state that the claims stand or fall together. Appeal Brief, page 2. Thus, we shall limit our consideration of the issues raised in this appeal as they pertain to claim 17, the only independent claim pending.

Claim 17 is directed to a method of making a medicament which comprises combining a steroidal aromatase inhibitor that contains no antigestagens and a substance for promoting skin penetration. The medicament is to be used for the prophylaxis or treatment of mastocarcinoma and the steroidal aromatase inhibitor must be present in a "therapeutically or prophylactically effective amount." Furthermore, the substance for promoting skin penetration is to avoid systemic action of the active ingredient.

Messenger describes a method for treating and preventing hair loss by topically administering an aromatase inhibitor to a mammal on the area to be treated. Id., abstract. The aromatase inhibitor is readily absorbed from the topically applied preparation into the skin and appropriate skin cells. Id., page 10. The aromatase

inhibitor may be formulated with suitable excipients. Id. The topically applied compositions of Messenger containing an aromatase inhibitor are formulated by simply combining the various compounds. See, e.g., Example 1.

Remington describes dimethyl sulfoxide as "[a]n aprotic solvent with remarkable properties to enhance penetrance of many locally applied drugs." Id., page 1218.

The examiner has concluded that it would have been prima facie obvious to a person of ordinary skill in the art to use a well known skin penetrant enhancing agent such as DMSO in the topically applied compositions of Messenger that contained an aromatase inhibitor.

Appellants disagree with the examiner's conclusion arguing that the examiner has "dismissed the preamble limitation that the medicament whose method of making is claimed is 'for the prophylaxis or treatment of mastocarcinoma' as not having patentable weight." Appeal Brief, page 8. Appellants argue "[t]he claimed method is not an open-ended method of combining two ingredients; rather, it is a method for making a medicament that, because of its particular claimed intended use, has certain characteristics which the method of making the medicament must be carried out to produce when the end product is used." Id.

In response, the examiner is of the opinion that the preamble language is merely an intended use and should not be given weight in determining the patentability of claim 17. Examiner's Answer, page 5.

In considering the issue raised in this appeal regarding the preamble, we find it to be much ado about nothing for, even if the preamble of claim 17 is to be given weight

as urged by appellants, claim 17 would have been obvious to a person of ordinary skill in the art from a consideration of Messenger and Remington.

We first note that the claim 17 does not require the composition formed by the method of combining set forth in claim 17 to be used in treating mastocarcinoma. Compare claim 17 on appeal with claim 1 discussed in In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976). Therefore, to the extent the preamble of claim 17 on appeal should be given weight, it would only be in terms of the amount of the aromatase inhibitor present in the resulting composition. Turning to the specification of this application, we find that a so-called "therapeutically or prophylactically effective amount of the aromatase inhibitor can be between 0.0001 and 20% by weight." Id., page 10. The aromatase inhibitor can be used in the compositions of Messenger in an amount of e.g., 0.2-10% w/v. Id., page 28. Thus, it appears that the amount of aromatase inhibitor present in the compositions described in Messenger is within the present definition of "therapeutically or prophylactically effective amount" and does not serve to distinguish the method of claim 17 from the method suggested by the prior art relied upon by the examiner.

We also note that the substance for promoting skin penetration, e.g., DMSO, is stated in claim 17 to "avoid systemic action of the active ingredient." As set forth above, Remington describes DMSO as having remarkable properties to enhance penetrance of many locally applied drugs. Since the aromatase inhibitor of Messenger is to be absorbed into appropriate skin cells, the use of DMSO in Messenger to assist with this function is clearly suggested. We find nothing in Remington to suggest that use of DMSO in the compositions described in Messenger would result in systemic action of

the aromatase inhibitor and claim 17 does not preclude the substance for promoting skin penetration from acting systemically itself.

We note that appellants also argue that "[p]ersons of ordinary skill in the art would not have been motivated by Messenger to administer steroidal aromatase inhibitors topically for treatment of mammary carcinoma." Appeal Brief, page 11. In response, we point out again that claim 17 does not require the actual application of the formed composition to a breast for treating mammary carcinoma. Claim 17 is not drafted in the manner of claim 1 under review in Hirao and as a consequence, the composition formed by claim 17 on appeal can be used for any purpose.

The examiner's rejection under 35 U.S.C. § 103(a) is affirmed.

Other Issue

We draw attention to U.S. Patent No. 5,945,109 (Schmidt). The two named inventors of Schmidt are the two inventors named in this application. Furthermore, the assignee listed on the first page of Schmidt is stated to be the Real Party In Interest in this appeal. Appeal Brief, page 1. Claims 1, 3, and 7 of Schmidt read as follows:

1. A cosmetic product for topical administration on skin over disturbed subcutaneous connective fatty tissue which comprises a substance which inhibits the formation and/or action of estrogens and which originates from soya glycins.

3. A cosmetic product as claimed in claim 1, wherein an aromatase inhibitor is present.

7. A cosmetic product as claimed in claim 1, wherein agents for promoting percutaneous absorption are furthermore present.

The compositions of Schmidt are formed by simply mixing the various constituents together. See, e.g., Example 3.

From these facts, it appears that Schmidt describes the mixing method required by claim 17 on appeal. The active ingredient in Schmidt, e.g., aromatase inhibitor, can be present in the amount of 0.0001 to 10 percent by weight while the substance for promoting skin penetration such as DMSO may be present in an amount of 1 to 25% by weight. Schmidt, column 5, line 55 - column 6, line 2. Thus, it is seen that Schmidt describes a method of making a composition by mixing the exact ingredients required by claim 17 on appeal in the same amounts.

Based upon the March 27, 1997 filing date of Schmidt, it does not appear that the patent is available as prior art. However, we have found of record PCT publication WO 97/36570 published on October 9, 1997. That document is in the German language but it does list as inventors the same two persons name as inventors in Schmidt and the present application. The company named as the Real Party of Interest in this appeal is listed as the owner/assignee of the published PCT document. Furthermore, the PCT publication lists as a priority document the same German document listed as a priority application on the face of Schmidt. Thus, it is reasonable to conclude on this record that the published PCT document WO 97/36570 is the same as or substantially the same as Schmidt. This is relevant because based upon the October 9, 1997 publication date, the PCT published application appears to be prior art to the present claims under 35 U.S.C. § 102(b).

If prosecution is resumed on this subject matter, appellants and the examiner should take into account the disclosure of PCT publication WO 97/36570 in determining the patentability of any claims presented.

The decision of the examiner is affirmed.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

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) INTERFERENCES

Barry E. Bretschneider
Morrison & Foerster
1650 Tysons Blvd., Suite 300
McLean, VA 22101

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